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10/765,402	01/27/2004	John Stephen Dunfield	100202073-1	2192

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EXAMINER	
RAZA, SAIRA B	
ART UNIT	**PAPER NUMBER**
1711	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,402	DUNFIELD ET AL.	
	Examiner	Art Unit	
	Saira Raza	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *31,35-38,41-45,58,62-65 and 68-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30,32,33,39,40,46-57,59,60,66 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/27/04 & 7/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's response to restriction requirement filed on October 25, 2005 is acknowledged. The arguments provided by the applicant have been considered valid, and therefore examiner withdraws the species election for components (a)-(d), (f)-(i) and (k). However, the species election for components (e) and (j) are upheld and are clearly restated below. (The letters (a)-(k) are in reference to the Election/Restriction Requirement mailed on November 6, 2005 by the examiner).

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

(e) core/encapsulated component of claims 31, 34-38, 41-45, and

(j) core/encapsulated component of claims 58, 61-65, 68-72.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. The election of an ultimate species for **each** of the aforementioned components is requested; in particular, please specify a single compound for the core/encapsulated component such as interleukin proteins or pancreatic cells.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. During a telephone conversation with Donald Coulman on November 29, 2005 a provisional election was made with traverse to prosecute hemoglobin as the core/encapsulating component, the elected species read on claims 34 and 61. Affirmation of this election must be made

by applicant in replying to this Office action. Claims 31, 35-38, 41-45, 58, 62-65, 68-72 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4-8, 11-14, 17, 18, 46, 47, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Loughman (WO 99/38535) (Page 9, Line 25 to Page 10, Line 35, Example VII).

6. In reference to claim 1 and 11, Loughman discloses a method for producing a microcapsule (referred to as a process of encasing the bound microparticles) comprising utilizing an ultrasonic atomizer where a dispersion of the first fluid (bound microparticles in an absorbable encasing polymer solution) is ejected as microdroplets into a second fluid (cooled non-solvent medium). The ultrasonic atomizer of Loughman functions as a fluid ejector and is activated at a frequency of 12 to 36kHz. Each activation of the ultrasonic atomizer generates a drop (having a volume), wherein the ultrasonic atomizer is fluidically coupled to a first fluid including a core component. Loughman discloses that the first fluid includes bound microparticles, the core component. For each drop of first fluid ejected into the second fluid, the result is the generation of a microcapsule in the second fluid, wherein the microcapsule includes the core component (Page 9, Line 25 to Page 10, Line 35, Example VII).

7. In reference to claim 2, each activation of the ultrasonic atomizer of Loughman generates a drop, hence the ultrasonic atomizer comprises activation of a drop on demand fluid ejector.

Wherein activation of any automated ultrasonic atomizer results in ejection of a drop, hence it is considered to comprise a drop on demand fluid ejector.

8. In reference to claim 4, 5, and 6, each activation of the ultrasonic atomizer of Loughman generates a drop. Hence it is inherent each activation results in the activation of an energy generating element one time, ejecting one drop of first fluid into said second fluid. Wherein if the energy generating element is activated n times, then n drops of first fluid will be ejected into second fluid, where n is an integer. The n drops resulting from the ultrasonic atomizer inherently produce a distribution of drop volumes within 6 or 10 percent of a specified volume.

9. In reference to claims 7 and 8, the ultrasonic atomizer of Loughman produces a drop with volume in the range of 1 atto-liter to about 1 pico-liter.

10. In reference to claims 12 and 13, it is inherent that activation of the ultrasonic atomizer of Loughman comprises application of an electrical pulse charging a nozzle through which first fluid is ejected, and applying a voltage pulse to deflect a pre-selected number of drops. The deflected pre-selected number of drops are ejected into a recirculator.

11. In reference to claim 14, the ejection of a drop is inherently a pre-selected distance above the surface of the second fluid.

12. In reference to claims 17 and 18, the ejection of a drop comprises ejecting a drop of first fluid from a chamber (referred to as homogenizer by Loughman) through one nozzle formed in a nozzle layer, wherein the chamber has a greater volume than the nozzle.

13. In reference to claim 46, Loughman discloses a method for producing a microcapsule (referred to as a process of encasing the bound microparticles) comprising utilizing an ultrasonic atomizer where a dispersion of the first fluid (bound microparticles in an absorbable encasing polymer solution) is ejected as microdroplets into a second fluid (cooled non-solvent medium). The

ultrasonic atomizer of Loughman functions as a fluid ejector and is activated at a frequency of 12 to 36kHz. Each activation of the ultrasonic atomizer generates a drop (having a volume), wherein the ultrasonic atomizer is fluidically coupled to a first fluid including a core component. Loughman discloses that the first fluid includes bound microparticles, the core component. For each drop of first fluid ejected into the second fluid, the result is the generation of a microcapsule in the second fluid, wherein the microcapsule includes the core component. Each activation of the ultrasonic atomizer of Loughman generates a drop. Hence it is inherent each activation results in the activation of an energy generating element one time, ejecting one drop of first fluid into said second fluid. Wherein if the energy generating element is activated n times, then n drops of first fluid will be ejected into second fluid, where n is an integer. The n drops resulting from the ultrasonic atomizer inherently produces a distribution of n fluid drop volumes, wherein each drop volume is said n fluid drops is within about 10 percent of a specified drop volume (Page 9, Line 25 to Page 10, Line 35, Example VII).

14. In reference to claim 47, Loughman discloses a method of using an ultrasonic atomizer (fluid ejection device) comprising: utilization and activation of a drop on demand fluid ejection device. Wherein each activation of the ultrasonic atomizer of Loughman generates a drop, hence the ultrasonic atomizer comprises utilization and activation of a drop on demand fluid ejector. Wherein activation of any automated ultrasonic atomizer results in ejection of a drop, hence it is considered to comprise a drop on demand fluid ejector. The drop on demand fluid ejection device of Loughman ejects essentially a drop of a first fluid including a microcapsule forming core component into a second fluid; specifically, the ultrasonic atomizer ejects the first fluid as microdroplets into the second fluid. Loughman discloses that the first fluid includes bound microparticles, the core component. For each drop of first fluid ejected into the second fluid, the result is the generation of a

microcapsule in the second fluid, wherein the microcapsule includes the core component (Page 9, Line 25 to Page 10, Line 35, Example VII).

15. In reference to claim 49, the ultrasonic atomizer of Loughman is inherently a pre-selected distance above the surface of the second fluid.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 3, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loughman (WO 99/38535) as applied to claim 1 above, and further in view of Boucher et al. (US Patent No. 6,641,254).

19. Loughman fails to teach that the fluid ejector activation further comprises activation of a thermal resistor or a piezoelectric element, wherein when the thermal resistor is utilized then at least

one component of the first fluid is heated above its boiling point. Hence attention is directed towards the Boucher reference.

20. Boucher teaches that it is well known in the fluid ejector art to utilize a fluid ejector comprising either a thermal resistor or a piezoelectric element, in order to utilize an energy generating element that produces the force necessary to eject the first fluid. Specifically, if the thermal resistor is employed, a component in the first fluid is rapidly heated above its boiling point causing ejection of a drop of the first fluid (2:2-10).

21. It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized the fluid ejector of Loughman with either a thermal resistor or a piezoelectric element in order to ensure sufficient force is present to eject the first fluid, as taught by Boucher.

22. Claims 29, 30, 32, 33, 34, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loughman (WO 99/38535) as applied to claim 1 above, and further in view of Wang (US Patent No. 5,462,866).

23. Loughman fails to teach the limitations of the first fluid and second fluid components, as well as the specifics of the generation of a microcapsule as stated in claims 29, 30, 34, 39, and 40. Hence attention is directed towards the Wang reference.

24. Wang discloses a process to form semipermeable microspheres encapsulating biological material. Specifically, the microspheres are formed via a fluid ejector. In reference to claim 29, the first fluid comprises a polyanion solution mixed with a core component (plastic beads). In reference to claim 40, the generation of the microcapsule in the second fluid comprises forming a coacervate. Specifically, the generation of the microcapsule comprises generation of a chitosan alkali metal alginate microcapsule, as in claim 39. In reference to claim 34, the core component of Wang comprises whole blood cells, which inherently contain hemoglobin. (6:30-40, Example 1 & 5). In

reference to claims 30, 32, and 33, Wang envisages a variety of components comprising the first and second fluid, one example includes a second fluid, which is immiscible in the first fluid. Another example is a first fluid including a core component and monomer and a second fluid including a core-reactant to the monomer, wherein the monomer and co-reactant form a polymer shell encapsulating the core component. One motivation for the selection of the aforementioned first and second fluids and the core component is to encapsulate biological material and to utilize polymers for the formation of polyelectrolyte complexes that are NIH approved for human implantation or that are naturally occurring water soluble polymers.

25. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the limitations of claims 29, 30, 32, 33, 34, 39, and 40 in the process of Loughman in view of the teachings of Wang in order to encapsulate biological materials and utilize polymer materials in the first and second fluid that are NIH approved for human implantation or that are naturally occurring water soluble polymers.

26. Claims 15, 16, 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loughman (WO 99/38535) as applied to claim 1 above.

27. In reference to claims 15, 16, 23 and 26-28, Loughman teaches the utilization of an ultrasonic atomizer, which ejects droplets of a first fluid into a second fluid. In reference to claims 15, 16, and 23, Loughman would contemplate the second fluid as a thin film in order to ensure minimal coating of the first fluid drop by the second fluid. The second fluid is stirred, resulting in the inherent flow of a thin film of the second fluid in a direction perpendicular to the axis of the fluid ejector head. In reference to claims 26-28 Loughman would contemplate the second fluid as a mist in order to ensure partial coating of the first fluid drop by the second fluid. In order to have the second fluid as a mist, it would have obvious to utilize the same fluid ejector as utilized to form a

drop of the first fluid. Specifically, it is necessary to activate a plurality of second fluid ejectors, which are coupled to the second fluid; the second fluid drops are ejected nearby to the drop of the first fluid, wherein the ejection from the plurality of second fluid ejectors results in the formation of a mist of the second fluid. Wherein if the same fluid ejectors are utilized for formation of droplets of the first and second fluids, it is inherent that the distribution of the second fluid drop volumes is within 10 percent of a specified second fluid drop volume.

28. It would have been obvious to one of ordinary skill at the time of the invention to form a microcapsule via the ultrasonic atomizer of Loughman, wherein the first fluid drop is ejected into either a thin film or a mist of the second fluid (in addition to the limitations in claims 16, 23, 27, and 28), in order to ensure minimal coating of the second fluid or ensure a partial shell around the first fluid drop.

29. In reference to claims 19, 20, 22, 24, 25, Loughman teaches the utilization of an ultrasonic atomizer, which ejects droplets of a first fluid into a second fluid. In reference to claim 19, Loughman would contemplate a portion of the nozzle of the ultrasonic atomizer below the surface of the second fluid in order to ensure engulfment of the first fluid drop by the second fluid. In reference to claim 20, the second fluid is stirred, resulting in the inherent flow of the fluid in a direction perpendicular to the axis of the fluid ejector head. In reference to claim 25 and 24, the nozzle and head of the ultrasonic atomizer is capable of movement, and Loughman would envisage reciprocally translating the fluid ejector in a lateral direction in the second fluid, in order to maximize the number of microcapsules formed. Specifically, the ultrasonic atomizer would move in one lateral direction either in or over the second fluid, become activated at a pre-selected location, and eject a drop of first fluid into second fluid at the pre-selected location.

30. It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized the ultrasonic atomizer of Loughman wherein a portion of the nozzle is below the surface of the second fluid and to reciprocally translate the fluid ejector (in addition to the limitations of claims 19, 20, 22, 24 and 25), in order to ensure engulfment of the first fluid drop by the second fluid and to maximize the number of microcapsules formed.

31. In reference to claims 21, Loughman teaches the utilization of an ultrasonic atomizer, which ejects droplets of a first fluid into a second fluid. The nozzle and head of the ultrasonic atomizer is capable of movement, and Loughman would envisage reciprocally translating the fluid ejector in a lateral direction over the second fluid, in order to maximize the number of microcapsules formed. Specifically, the ultrasonic atomizer would move in one lateral direction over the second fluid, become activated at a pre-selected location, and eject a drop of first fluid into second fluid at the pre-selected location.

32. It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the ultrasonic atomizer of Loughman and to reciprocally translate the fluid ejector in order to maximize the number of microcapsules formed.

33. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Loughman (WO 99/38535) as applied to claim 47 above, and further in view of Boucher et al. (US Patent No. 6,641,254).

34. Loughman fails to teach that the energizing the fluid ejector further comprises energizing or activating a thermally activated fluid ejector. Hence attention is directed towards the Boucher reference.

35. Boucher teaches that it is well known in the fluid ejector art to utilize a fluid ejector comprising either a thermal resistor, in order to utilize an energy generating element that produces

the force necessary to eject the first fluid and to rapidly heat a component in the first fluid above its boiling point causing ejection of a drop of the first fluid (2:2-10). Hence activation of Boucher's fluid ejector comprising a thermal resistor is considered energizing a thermally activated fluid ejector.

36. It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized the fluid ejector of Loughman with a thermal resistor in order to ensure sufficient force is present to eject the first fluid and to rapidly heat a component in the first fluid above its boiling point causing ejection of a drop of the first fluid, as taught by Boucher.

37. In reference to claims 50, 51, 52, 53, 54 and 55 Loughman teaches the utilization of an ultrasonic atomizer, which ejects droplets of a first fluid into a second fluid. In reference to claim 50, Loughman would contemplate a portion of the nozzle of the ultrasonic atomizer below the surface of the second fluid in order to ensure engulfment of the first fluid drop by the second fluid. In reference to claims 51, the second fluid is stirred, resulting in the inherent flow of the fluid in a direction perpendicular to the axis of the fluid ejector head. In reference to claims 52, 53, and 54 the nozzle and head of the ultrasonic atomizer is capable of movement, and Loughman would envisage reciprocally translating the fluid ejector in a lateral direction either in or over the second fluid, in order to maximize the number of microcapsules formed. Specifically, the ultrasonic atomizer would move in one lateral direction either in or over the second fluid, become activated at a pre-selected location, and eject n drops of first fluid into second fluid at n pre-selected lateral locations. In reference to claim 55, Loughman would contemplate the second fluid as a thin film in order to ensure minimal coating of the first fluid drop by the second fluid.

38. It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized the ultrasonic atomizer of Loughman wherein a portion of the nozzle is below or over the surface of the second fluid and to reciprocally translate the fluid ejector (in addition to the

limitations of claims 50-55), in order to ensure engulfment of the first fluid drop by the second fluid, to maximize the number of microcapsules formed, and to ensure minimal coating of the first fluid drop by the second fluid.

39. Claims 56, 57, 59, 60, 61, 66, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loughman (WO 99/38535) as applied to claim 47 above, and further in view of Wang (US Patent No. 5,462,866).

40. Loughman fails to teach the limitations of the first fluid and second fluid components, as well as the specifics of the generation of a microcapsule as stated in claims 56, 57, 61, 66, and 67. Hence attention is directed towards the Wang reference.

41. Wang discloses a process to form semipermeable microspheres encapsulating biological material. Specifically, the microspheres are formed via a fluid ejector. In reference to claim 56, the first fluid comprises a polyanion solution mixed with a core component (plastic beads). In reference to claim 67, the generation of the microcapsule in the second fluid comprises forming a coacervate. Specifically, the generation of the microcapsule comprises generation of a chitosan alkali metal alginate microcapsule, as in claim 66. In reference to claim 61, the core component of Wang comprises whole blood cells, which inherently contain hemoglobin. (6:30-40, Example 1 & 5). In reference to claims 57, 59, and 60, Wang envisages a variety of components comprising the first and second fluid, one example includes a second fluid, which is immiscible in the first fluid. Another example is a first fluid including a core component and monomer and a second fluid including a core-reactant to the monomer, wherein the monomer and co-reactant form a polymer shell encapsulating the core component. One motivation for the selection of the aforementioned first and second fluids and the core component is to encapsulate biological material and to utilize polymers

for the formation of polyelectrolyte complexes that are NIH approved for human implantation or that are naturally occurring water soluble polymers.

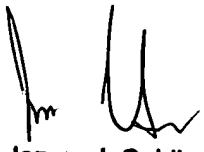
Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the limitations of claims 56, 57, 59, 60, 61, 66, and 67 in the process of Loughman in view of the teachings of Wang in order to encapsulate biological materials and utilize polymer materials in the first and second fluid that are NIH approved for human implantation or that are naturally occurring water soluble polymers.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saira Raza whose telephone number is (571) 272-3553. The examiner can normally be reached on Monday-Friday from 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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